

Coordinating Agency:

Department of Health and Human
Services

Cooperating Agencies:

Department of Agriculture
Department of Commerce
Department of Defense
Department of Energy
Department of Homeland Security
Department of the Interior
Department of Justice
Department of Labor
Department of State
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
General Services Administration
U.S. Agency for International Development
U.S. Postal Service
American Red Cross

INTRODUCTION

Purpose

The purpose of the Biological Incident Annex is to outline the actions, roles, and responsibilities associated with response to a disease outbreak of known or unknown origin requiring Federal assistance. A biological incident includes naturally occurring biological diseases (communicable and noncommunicable in humans and those biological agents diagnosed in animals having the potential for transmission to humans (zoonosis)) as well as terrorist events. Actions described in this annex take place with or without a Presidential Stafford Act declaration or a public health emergency declaration by the Secretary of Health and Human Services (HHS). This annex outlines biological incident response actions including threat assessment notification procedures, laboratory testing, joint investigative/response procedures, and activities related to recovery.

Scope

The objectives of the Federal Government's response to a biological terrorism event, pandemic influenza, emerging infectious disease, or novel pathogen outbreak are to:

- Detect the event through disease surveillance and environmental monitoring.
- Identify and protect the population(s) at risk.
- Determine the source of the outbreak.
- Quickly frame the public health, law enforcement, and international implications.
- Control and contain any possible epidemic (including providing guidance to State, tribal, and local public health authorities).
- Augment and surge public health and medical services.

- Identify the cause and prevent the recurrence of any potential resurgence or additional outbreaks.
- Assess the extent of residual biological contamination and decontaminate as necessary.

The unique attributes of this response require separate planning considerations that are tailored to specific health concerns and effects of the disease (e.g., terrorism versus natural outbreaks, communicable versus noncommunicable, etc.).

Specific operational guidelines, developed by respective organizations to address the unique aspects of a particular biological agent or planning consideration, will supplement this annex and are intended as guidance to assist Federal, State, tribal, and local public health and medical planners.

In this document, the term “public health and medical” is inclusive of relevant terms, including veterinary medical.

Special Considerations

Detection of a bioterrorism act against the civilian population may occur in several different ways and involve several different modalities:

- An attack may be surreptitious, in which case the first evidence of dissemination of an agent may be the presentation of disease in humans or animals. This could manifest either in clinical case reports to domestic or international public health authorities or in unusual patterns of symptoms or encounters within domestic or international health surveillance systems.
- A terrorist-induced infectious disease outbreak initially may be indistinguishable from a naturally occurring outbreak; moreover, depending upon the particular agent and associated symptoms, several days could pass before public health and medical authorities even suspect that terrorism may be the cause. In such a case, criminal intent may not be apparent until some time after illnesses are recognized.
- Environmental surveillance systems, such as the BioWatch system, may detect the presence of a biological agent in the environment and trigger directed environmental sampling and intensified clinical surveillance to rule out or confirm an incident. If confirmed, the utilization of environmental surveillance systems may allow for mobilization of a public health, medical, and law enforcement response in advance of the appearance of the first clinical cases or a rapid response after the first clinical cases are identified.
- Other cooperating departments and agencies listed in this annex may detect acts of bioterrorism or biological incidents through their normal operations and surveillance efforts. Should this occur, notifications should be made according to approved interagency response protocols, consistent with the health and law enforcement assessment process described in this annex.

Policies

This annex supports policies and procedures outlined in the National Response Framework, Emergency Support Function (ESF) #8 – Public Health and Medical Services Annex, ESF #10 – Oil and Hazardous Materials Response Annex, ESF #11 – Agriculture and Natural Resources Annex, ESF #15 – External Affairs Annex, the Terrorism Incident Law Enforcement and Investigation Annex, and the International Coordination Support Annex.

HHS serves as the Federal Government's primary agency for the public health and medical preparation and planning for and response to a biological terrorism attack or naturally occurring outbreak that results from either a known or novel pathogen, including an emerging infectious disease.

The Department of Agriculture (USDA) serves as the Government's primary agency for outbreaks and/or attacks which may occur in animals used in the commercial production of food. In the event of an animal event, HHS may provide additional public health and veterinary epidemiological assistance to USDA. Wildlife events will be placed under the purview of the Department of the Interior (DOI), while those involving marine animals will be managed and monitored by the Department of Commerce.

State, tribal, and local governments are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the health, social, and economic consequences of such an outbreak.

If any agency or government entity becomes aware of an overt threat involving biological agents or indications that instances of disease may not be the result of natural causes, the Department of Justice (DOJ) must be notified through DOJ/Federal Bureau of Investigation (FBI)'s Weapons of Mass Destruction Operations Unit (WMDOU). If the threat is deemed credible by DOJ/FBI in coordination with HHS or USDA, DOJ/FBI, in turn, immediately notifies the National Operations Center (NOC) and the National Counterterrorism Center (NCTC). The Laboratory Response Network (LRN) is used to test samples for the presence of biological threat agents. Decisions on where to perform additional tests on samples are made by DOJ/FBI, in coordination with HHS or USDA.

Once notified of a credible threat or natural disease outbreak, HHS convenes a meeting of ESF #8 partners to assess the situation and determine appropriate public health and medical actions. The Department of Homeland Security (DHS) coordinates overall nonmedical support and response actions across all Federal departments and agencies. HHS leads public health and medical emergency response efforts across all Federal departments and agencies.

DOJ/FBI coordinates the investigation of criminal activities if such activities are suspected.

HHS provides guidance to State, tribal, and local authorities and collaborates closely with DOJ/FBI in the proper handling of any materials that may have evidentiary implications (e.g., LRN samples, etc.) associated with disease outbreaks suspected of being terrorist or criminal in nature. If evidentiary materials are shared with or procured from foreign governments, HHS and DOJ/FBI will coordinate and share information with the Department of State (DOS) as appropriate.

Other Federal departments and agencies may be called upon to support HHS during the various stages of a disease outbreak response in the preparation, planning, and/or response processes.

If there is potential for environmental contamination, HHS collaborates with the Environmental Protection Agency (EPA) in developing and implementing sampling strategies and sharing results.

In the event of an outbreak of an agriculturally significant zoonotic disease, HHS collaborates with USDA during the preparation, planning, and/or response processes.

Given the dynamic nature of a disease outbreak, HHS, in collaboration with other departments and agencies, determines the thresholds for a comprehensive Federal Government public health and medical response. These thresholds are based on specific event information rather than predetermined risk levels.

Any Federal public announcement, statement, or press release related to a threat or actual bioterrorism event must be coordinated with the DHS Office of Public Affairs and ESF #15, if activated.

Planning Assumptions

In a large disease outbreak, Federal, State, tribal, and local officials require a highly coordinated response to public health and medical emergencies. The outbreak also may affect other countries, or be of international concern, and therefore involve extensive coordination with DOS and the international health community (e.g., the World Health Organization (WHO)).

Disease transmission can occur via an environmental contact such as atmospheric dispersion, person-to-person contact, animal-to-person contact, insect vector-to-person contact, or by way of contaminated food or water.

A biological incident may be distributed across multiple jurisdictions simultaneously, requiring a nontraditional incident management approach. This approach could require the simultaneous management of multiple "incident sites" from national and regional headquarters locations in coordination with multiple State, tribal, and local jurisdictions.

A response to noncontagious public health emergencies may require different planning assumptions or factors.

The introduction of biological agents, both natural and deliberate, are often first detected through clinical or hospital presentation. However, there are other methods of detection, including environmental surveillance technologies such as BioWatch and syndromic surveillance.

Routine fish and wildlife health and disease surveillance, including investigation of wildlife mortality events conducted on public lands and in public laboratories, provides the opportunity for early detection of biological agents and acts of bioterrorism.

No single entity possesses the authority, expertise, and resources to act unilaterally on the many complex issues that may arise in response to a disease outbreak and loss of containment affecting a multijurisdictional area. The national response requires close coordination between numerous agencies at all levels of government and with the private sector.

The Federal Government supports affected State, tribal, and local health jurisdictions as requested or required. The response by HHS and other Federal agencies is flexible and adapts as necessary as the outbreak evolves.

The LRN provides analytical support to inform public health assessment of the potential for human illness associated with exposure and the scope of this kind of risk. The LRN also provides for definitive testing of both environmental and clinical samples resulting in law enforcement notification for threat assessment of criminal intent while ensuring chain of custody. Early HHS, DOJ/FBI, USDA, and DHS coordination enhances the likelihood of successful preventative and investigative activities necessary to neutralize threats and attribute the source of the outbreak.

Response to disease outbreaks suspected of being deliberate in origin requires consideration of special law enforcement and homeland security requirements as well as international legal obligations and requirements.

Test results from non-LRN facilities are considered a “first pass” or “screening” test (with the exception of the Legislative Branch, which has a separate lab system that is equivalent to LRN facilities).

Any agency or organization that identifies an unusual or suspicious test result should contact DOJ/FBI to ensure coordination of appropriate testing at an LRN laboratory.

HHS has identified specific Department of Defense laboratories that meet the standards and requirements for LRN membership.

All threat and public health assessments are provided to the NOC.

CONCEPT OF OPERATIONS

Biological Agent Response

The key elements of an effective biological response include (in nonsequential order):

- Rapid detection of the outbreak.
- Rapid dissemination of key safety information and necessary medical precautions.
- Swift agent identification and confirmation.
- Identification of the population at risk (to include animals and marine life).
- Determination of how the agent is transmitted, including an assessment of the efficiency of transmission.
- Determination of susceptibility to prophylaxis and treatment.
- Definition of the public health and medical services, human services, and mental health implications.
- Control and containment of the epidemic.
- Decontamination of individuals, if necessary.
- Identification of the law enforcement implications/assessment of the threat.
- Augmentation and surging of local health and medical resources.
- Protection of the population through appropriate public health and medical actions.
- Dissemination of information to enlist public support.

- Response options may include assessment of environmental contamination and cleanup/decontamination of bioagents that persist in the environment; and providing consultation on the safety of food products that may be derived from directly or environmentally exposed animals or marine life.
- Tracking and preventing secondary or additional disease outbreak.

Primary Federal functions include supporting State, tribal, and local public health and medical capacities according to the policies and procedures detailed in the National Response Framework and its annexes (e.g., ESF #8).

Suspicious Substances

Since there is no definitive/reliable field test for biological agents, all potential bioterrorism samples are transported to an LRN laboratory, where expert analysis is conducted using established HHS protocols/reagents. A major component of this process is to establish and maintain the law enforcement chain of custody and arrange for transport.

The following actions occur if a positive result is obtained by an LRN on an environmental sample submitted by DOJ/FBI or other designated law enforcement personnel:

- The LRN immediately notifies the local DOJ/FBI of the positive test result.
- The DOJ/FBI Field Office makes local notifications and contacts the DOJ/FBI Headquarters WMDOU.
- DOJ/FBI Headquarters convenes an initial conference call with the local DOJ/FBI, HHS, and appropriate response officials to review the results, assess the preliminary information and test results, and arrange for additional testing.
- DOJ/FBI Headquarters immediately notifies DHS of the situation.
- Original samples may be sent to HHS/Centers for Disease Control and Prevention for confirmation of LRN analyses.
- HHS provides guidance on protective measures such as prophylaxis, treatment, and continued facility operation.
- HHS, the EPA, and cooperating agencies support the determination of the contaminated area, decisions on whether to shelter in place or evacuate, and decontamination of people, animals, facilities, and outdoor areas.

Outbreak Detection

Determination of a Disease Outbreak

The initial indication of a major disease outbreak, intentional or naturally occurring, may be the recognition by public health and medical authorities that a significantly increased number of people are becoming ill and presenting to local healthcare providers.

One tool to support this process is the National Biosurveillance Integration System (NBIS). NBIS leverages the individual capabilities of multiple surveillance systems by integrating and analyzing domestic and international surveillance and monitoring data collected from human health, animal health, plant health, food and water and monitoring systems. This integrated cross-domain analysis allows for enhanced situational awareness and potentially reduced detection time, thus enabling more rapid and effective biological incident response decisionmaking.

As a result of the nature in which a disease outbreak may be recognized, critical decisionmaking support requires integrated surveillance information, identification of the causative biological agent, a determination of whether the observations are related to a naturally occurring outbreak, and identification of the population(s) at risk.

Laboratory Confirmation

During the evaluation of a suspected disease outbreak, laboratory samples are distributed to appropriate laboratories. During a suspected terrorist incident, sample information is provided to DOJ/FBI for investigative use and to public health and emergency response authorities for epidemiological use and agent characterization to facilitate and ensure timely public health and medical interventions. If the incident begins as an epidemic of unknown origin detected through Federal, State, tribal, or local health surveillance systems or networks, laboratory analysis is initiated through the routine public health laboratory system.

Identification (Analysis and Confirmation)

The samples collected and the analyses conducted must be sufficient to characterize the cause of the outbreak. LRN laboratories fulfill the Federal responsibility for rapid analysis of biological agents. In a suspected terrorism incident, sample collection activities and testing are coordinated with DOJ/FBI and LRN member(s).

Notification

Any disease outbreak suspected or identified by an agency within HHS or through another Federal public health partner is brought to the immediate attention of the HHS (as detailed in the ESF #8 Annex), in addition to the notification requirements contained in the National Response Framework.

Any potential biological agent, disease outbreak, or suspected bioterrorism act affecting or involving animals, plant health, or wildlife should involve notifications to USDA (animals and plant health) and DOI (wildlife).

Following these initial notifications, the procedures detailed in the ESF #8 Annex are followed. Instances of disease that raise the "index of suspicion" of terrorist or criminal involvement, as determined by HHS or USDA (for animal and plant diseases), are reported to DOJ/FBI Headquarters. In these instances, DOJ/FBI Headquarters, in conjunction with HHS and/or USDA, examines available law enforcement and intelligence information, as well as the

technical characteristics and epidemiology of the disease, to determine if there is a possibility of criminal intent. If DOJ/FBI, in conjunction with HHS or USDA, determines that the information represents a potential credible terrorist threat, DOJ/FBI communicates the situation immediately to the NCTC and NOC, which notifies the White House, as appropriate. If warranted, DOJ/FBI, HHS, and/or USDA and respective State, tribal, and/or local health officials will conduct a joint law enforcement and epidemiological investigation to determine the cause of the disease outbreak, the extent of the threat to public health and public safety, and the individual(s) responsible.

In the event of an environmental detection of a biological threat agent above established agency-specific thresholds, the responsible agency should contact HHS, DOJ/FBI, and the NOC within 2 hours of laboratory confirmation. DOJ/FBI, in conjunction with HHS, will convene a threat assessment conference call to examine the potential threat and public health risk posed by the detection. Coordination of assessment and response activities will involve officials from the impacted State and local jurisdiction(s).

Activation

Once notified of a threat or disease outbreak that requires or potentially requires significant Federal public health and medical assistance, HHS convenes a meeting of its internal components and the ESF #8 partner organizations to assess the situation and determine the appropriate public health and medical actions. DHS coordinates all nonmedical support, discussions, and response actions.

The immediate task following any notification is to identify the population affected and vulnerable and the geographic scope of the incident. The initial public health and medical response includes some or all of the following actions:

- Targeted epidemiological investigation (e.g., contact tracing).
- Dissemination of key safety information and necessary medical precautions.
- Intensified surveillance within healthcare settings for patients with certain clinical signs and symptoms.
- Intensified collection and review of potentially related information (e.g., contacts with nurse call lines, laboratory test orders, school absences, over-the-counter pharmacy sales, unusual increase in sick animals, wildlife deaths, decreased commercial fish yields).
- Organization of Federal public health and medical response assets (in conjunction with State, tribal, and local officials) to include personnel, medical and veterinary supplies, and materiel (e.g., the Strategic National Stockpile (SNS) and Veterinary Stockpiles).

If there is suspicion that the outbreak may be deliberate, DOJ/FBI may establish a Joint Operations Center (JOC), which may be integrated into the Joint Field Office structure, if established, to coordinate investigative and intelligence activities among Federal, State, tribal, and local authorities. Within the JOC structure locally, and DOJ/FBI's Strategic Information and Operations Center in Washington, DC, responsible public health officials would be integrated into the command structure to coordinate the interaction between law enforcement and public health investigations.

ACTIONS

Controlling the Epidemic

The following steps are required to contain and control an epidemic affecting large populations:

- HHS assists State, tribal, and local public health and medical authorities with epidemic surveillance and coordination.
- HHS assesses the need for increased surveillance in State, tribal, and local entities not initially involved in the outbreak and notifies the appropriate State and local public health officials with surveillance recommendations should increased surveillance in these localities be needed.
- DHS coordinates with HHS and State, tribal, and local officials on the messages released to the public to ensure that communications are consistent timely, consistent, accurate, and actionable. Messages should address anxieties, alleviate any unwarranted concerns or distress, and enlist cooperation with necessary control measures. Public health and medical messages to the public should be communicated by a recognized health authority (e.g., the U.S. Surgeon General). (See the Public Affairs Support Annex.)
- Consistent with the International Health Regulations, if the outbreak first arises within the United States, HHS, in coordination with DOS, immediately notifies and coordinates with appropriate international health agencies. Given the nature of many disease outbreaks, this notification and coordination may have occurred earlier in the process according to internal operating procedures. HHS advises the NOC when notifications are made to international health agencies.
- The public health system, starting at the local level, is required to initiate appropriate protective and responsive measures for the affected population, including first responders and other workers engaged in incident-related activities. These measures include mass vaccination or prophylaxis for populations at risk and populations not already exposed, but who are at risk of exposure from secondary transmission or the environment. An overarching goal is to develop, as early as possible in the management of a biological incident, a dynamic, prioritized list of treatment recommendations based on epidemiologic risk assessment and the biology of the disease/microorganism in question, linked to the deployment of the SNS and communicated to the general public.
- HHS evaluates the incident with its partner organizations and makes recommendations to the appropriate public health and medical authorities regarding the need for isolation, quarantine, or shelter-in-place to prevent the spread of disease. HHS will also coordinate with volunteer personnel, such as the Medical Reserve Corps and the Emergency Management Assistance Compact.
- The Governor of an affected State implements isolation and/or social-distancing requirements using State/local legal authorities. The tribal chief executive of a recognized tribe may also order a curfew, isolation, social distancing, and quarantine under tribal legal authorities. In order to prevent the import or interstate spread of disease, HHS may take appropriate Federal actions using the authorities granted by title 42 of the U.S. Code, 42 CFR parts 70 and 71, and 21 CFR part 1240. State, tribal, and local assistance with the implementation and enforcement of isolation and/or quarantine actions is utilized if Federal authorities are invoked.

- Where the source of the disease outbreak has been identified as originating outside the United States, whether the result of terrorism or a natural outbreak, HHS works in a coordinated effort with DHS to identify and isolate persons, cargo, mail, or conveyances entering the United States that may be contaminated.
- The scope of the disease outbreak may require mass isolation or quarantine of affected or potentially affected persons. Depending on the type of event, food, animals, and other agricultural products may need to be quarantined to prevent further spread of disease. In this instance HHS and, as appropriate, USDA will work with State, tribal, and local health and legal authorities to recommend the most feasible, effective, and legally enforceable methods of isolation and quarantine. In the event that foreign nationals are subject to isolation and/or quarantine, HHS will work through DOS to notify affected foreign governments.

Decontamination

For certain types of biological incidents (e.g., anthrax), it may be necessary to assess the extent of contamination and decontaminate victims, responders, animals, equipment, buildings, critical infrastructure, and large outdoor areas. Such decontamination and related activities take place consistent with the roles and responsibilities, resources and capabilities, and procedures contained in the ESF #8, ESF #10, and ESF #11 Annexes, the Terrorism Incident Law Enforcement and Investigation Annex, and the Catastrophic Incident Annex. (Note: Currently no decontamination chemicals are registered (under the Federal Insecticide, Fungicide, and Rodenticide Act) for use on biological agents and responders must request an emergency exemption from the EPA before chemicals can be used for biological decontamination.)

Special Issues

International Notification/Implications

A biological incident may involve internationally prescribed reportable diseases. In addition to case reporting, epidemics of disease with global public health significance must also be reported to international public health authorities. A biological incident may also have implications under the Biological Weapons Convention if it can be attributed to actions of a foreign party, in which case, DOS would manage the diplomatic aspects of any such case.

Consistent with the International Health Regulations, once a positive determination is made of an epidemic involving a contagious biological agent, HHS notifies DOS and DHS. HHS, in coordination with DOS, notifies the WHO and other international health agencies as appropriate.

Allocation and Rationing

If critical resources for protecting human life are insufficient to meet all domestic needs, the Secretary of HHS makes recommendations to the Secretary of Homeland Security regarding the allocation of scarce Federal public health and medical resources.

RESPONSIBILITIES

The procedures in this annex are built on the core coordinating structures of the National Response Framework. The specific responsibilities of each department and agency are described in the respective ESF and Incident Annexes.